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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,836	06/08/2001	Osamu Yamada	19036/37156	3756

7590 01/28/2003
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EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 01/28/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,836

Applicant(s)

YAMADA ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-24, 26, 28-31, 33-39, 44, 45 and 47-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21, 23, 24, 26, 28, 33-39 and 52-55 is/are allowed.
- 6) ☒ Claim(s) 22, 29, 30, 44, 45, 47-51 and 56 is/are rejected.
- 7) ☒ Claim(s) 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 June 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>13</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Non-Final Office Action is a response to the “Amendment in Response to Office Action” filed 15 October 2002 (Paper No. 15) in response to the Non-Final Office Action mailed 10 April 2002 (Paper No. 12). Claims 1-6, 8-18 and 20-46 were considered in Paper No. 12. Claims 1-18, 20, 25, 27, 32, 40-43 and 46 were canceled, claims 21-24, 26, 28, 30, 31, 33-39, 44 and 45 were amended and claims 47-56 were added in Paper No. 15. Claims 21-24, 26, 28-31, 33-39, 44, 45 and 47-56 are pending and under consideration.

Drawings

The drawings stand objected to for the reasons indicated on the PTO-948 mailed with Paper No. 12. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the “Notice of Allowability.” Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

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All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Response to Amendment

All rejections as they pertain to claims 1-18, 20, 25, 27, 32, 40-43 and 46 are rendered moot by the cancellation of the claims in Paper No. 15.

Rejection of claims 35, 36 and 37 under 35 U.S.C. § 112, first paragraph, as lacking enablement is withdrawn.

Claim 30 stands rejected and claim 29 is newly rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement commensurate with the full scope of the claimed subject matter for reasons of record in Paper No. 12.

Rejection of claims 21-24, 26, 33, 38, 39, 44 and 45 under 35 U.S.C. § 112, second paragraph, for reasons of record in Paper No. 12 is withdrawn.

Claims 22, 44, 45, 47-51 and 56 are newly rejected under 35 U.S.C. § 112, second paragraph.

Rejection of claims 21, 22, 28, 29, 31, 35, 44 and 45 under 35 U.S.C. § 102(b) as anticipated by Yoo *et al.* is withdrawn.

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Rejection of claims 23-25 under 35 U.S.C. § 102(b) as anticipated by Collier *et al.* is withdrawn.

Rejection of claims 33 and 34 under 35 U.S.C. § 102(b) as anticipated by Zhang is withdrawn.

Rejection of claims 23 and 24 under 35 U.S.C. § 103(a) as obvious over Brown *et al.* and Dirks *et al.* in view of Fukushi *et al.* is withdrawn.

Response to Arguments

35 U.S.C. § 112, first paragraph, enablement

Claims 29 and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated host cell transformed or transfected with the vector according to claim 28 and a method of expressing a protein *in vitro*, does not reasonably provide enablement for a host cell *in vivo* or a method of expressing a protein *in vivo*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claim 30 was rejected in Paper No. 12 in part because the claim encompasses a method of expressing a protein *in vivo* and thus gene therapy (see especially the first paragraph on page 4). Applicant traverses on the grounds that the specification and prior art teaches methods of protein expression and the claimed method can be used to express useful proteins. While applicant's point is taken and the claims are enabled to the extent that the method can be used to express a protein *in vitro*, teachings in the specification (especially pages 15-17) clearly contemplate methods of protein expression *in vivo* for therapeutic purposes. As the only real-

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world utility contemplated for the claimed method of expressing a protein *in vivo* is gene therapy, and gene therapy is not enabled for the reasons of record in Paper No. 12, claim 30 is not enabled for expressing a protein *in vivo*. For the same reasons, claim 29 is not enabled to the extent that the claim reads on a host cell *in vivo*.

New Grounds

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22, 44, 45, 47-51 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22, 44 and 45 are indefinite in their recitation of enhancing “expression of a nucleic acid sequence”. The teachings of the specification indicate that the invention is based on a polynucleotide sequence that enhances translation from a polynucleotide. There are no teachings to the effect that the nucleic acid sequence enhances expression of the polynucleotide itself. Appropriate correction or clarification is required.

Claim 45 is also indefinite in its recitation of “a sequence derived from a wild-type virus” in line 4. Without a clear statement of the process by which a starting material is derivatized it is not possible to know the metes and bounds of such a limitation because any given starting material can have many divergent derivatives depending on the process of derivatization.

Claim 45 is also indefinite because it is unclear how the claim further limits the claims from which it depends. Claim 45 is directed to a polynucleotide comprising a nucleic acid sequence which comprises the nucleotide sequence of SEQ ID NO:7, at least one region selected from the group consisting of pyrimidine-rich tract, Box A, Box B, a trans factor-binding site, and a combination thereof, wherein said nucleic acid comprises a sequence having substitution, deletion, insertion and/or addition of a single or a few nucleotides of a sequence derived from a wild type virus within the sequence or proximate sequence in at least one position corresponding to a pyrimidine-rich tract, Box A, Box B and/or trans factor binding site contained in the 5'-untranslated region. Given its broadest reasonable interpretation, wherein a few nucleotides can be two or more and "a sequence derived from a wild type virus" can be any sequence, the claim is limited only to an isolated polynucleotide comprising the sequence set forth as SEQ ID NO:7 and infinite variations of additional nucleotide sequence. Thus, it is not clear how claim 45 differs from claim 24, which is directed to a polynucleotide comprising SEQ ID NO:7.

Claims 47-51 are indefinite in their recitation of "the 5'-untranslated region". There is no antecedent basis for the limitation in claim 24, from which the claims depend.

Claim 56 is indefinite in its recitation of "said gene expressing vector". There is no antecedent basis for a gene expressing vector in claim 55.

Allowable Subject Matter

Claims 21, 23, 24, 26, 28, 33-39, and 52-55 are allowed.

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Claim 31 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
January 17, 2003


**JAMES KETTER
PRIMARY EXAMINER**